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SUMMARY OF SAFETY AND EFFECTIVENESS

Vitamin B_{12} Method for TECHNICON IMMUNO-1® System

Listed below is a comparison of the performance between the IMMUNO-1 B_{12} method and a similar device that was granted clearance of substantial equivalence (BioRad Quantaphase radioassay method). The information used in the Summary of Safety and Effectiveness was extracted from the IMMUNO-1 B_{12} method sheets and from data on file at Miles, Inc.

INTENDED USE

This *in vitro* diagnostic procedure is intended to quantitatively measure Vitamin B_{12} in human serum on the Technicon IMMUNO-1® system. Measurements of Vitamin B_{12} are used in the diagnosis and treatment of anemia.

METHOD	IMMUNO-1 B_{12}	BioRad Quantaphase (predicate Device)
Part No.	T01-3462-01	192 5001
Minimum Detectable Conc.	25 pg/mL	20 pg/mL
Precision (Between-Run)	170 pg/mL 10.1% 250 pg/mL 7.4% 1000 pg/mL 6.0%	157 pg/mL 8.3% 477 pg/mL 2.7% 1239 pg/mL 2.7%
Linearity	0 - 2000 pg/mL	0 - 2000 pg/ml
Correlation	$y = 0.95 x + 19$ where y = IMMUNO-1 B_{12} assay; x = BioRad Quantaphase method n = 46 r = 0.99 S_{yx} = 40 pg/mL	
SPECIFICITY*		
(Cross-Reactivity of cobinamide)	< 26 pg/mL	< 66 pg/mL

* The cross-reactivity of cobinamide was determined by assaying several samples before and after spiking with 10,000 pg/mL cobinamide. The data shown are the maximum net change in assayed B_{12} level.